Attorney's Docket No.: 20750-041US1 / 059.US2.PCT



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Graeme Semple, et al.

Art Unit : Unknown

Serial No.: 10/560,332

Examiner: Unknown

Filed

: December 9, 2005

Conf. No.: 9629

Title

: 5-SUBSTITUTED 2H-PYRAZOLE-3-CARBOXYLIC ACID DERIVATIVES AS

AGONISTS FOR THE NICOTINIC ACID RECEPTOR RUP25 FOR THE

TREATMENT OF DYSLIPIDEMIA AND RELATED DISEASES

MAIL STOP AMENDMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Applicants request consideration of the references listed on the attached PTO-1449 form. Under 37 C.F.R. § 1.98 (a)(2)(ii), only copies of foreign patent documents and/or non-patent literature are enclosed. Copies of any listed U.S. patents or U.S. patent application publications can be provided upon request. A copy of a communication from a foreign patent office in a counterpart application is also enclosed.

Inclusion of the information submitted herewith is not to be construed as an admission that the information is material as that term is defined in 37 C.F.R. § 1.56(b).

In accordance with 37 C.F.R. § 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

This statement is being filed within three months of the filing date of the application or before the receipt of a first Office Action on the merits. Please apply any charges or credits to Deposit Account No. 06-1050.

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Applicant: Graeme Semple, et al.

Serial No.: 10/560,332

: December 9, 2005 Filed

: 2 of 2 Page

Respectfully submitted,

Reg. No. 46,731

Attorney's Docket No.: 20750-041US1 / 059.US2.PCT

Date: February 22, 2007

Fish & Richardson P.C. 225 Franklin Street Boston, MA 02110

Telephone: (617) 542-5070 Facsimile: (617) 542-8906

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				Application Number	10/560,332	(F
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STA	TEMENT I	BY A	PPLICANT	First Named Inventor	Graeme Semple	18
				Art Unit	1614	
	(Use as many s	heets as	necessary)	Examiner Name	Unknown	
Sheet	1	of	15	Attorney Docket Number	59.US2.PCT	

			U.S. PATENT D	OCUMENTS	•
Examiner	Cite	Document Number	Publication/Issue Date	Name of Patentee or Applicant of	Pages, Columns, Lines, Where Relevant
Initials *	No.1	Number - Kind Code ² (if known)	MM-DD-YYYY	Cited Document	Passages or Relevant Figures Appear
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<u> </u>	AN	WO 2004/085401 A1	10-07-2004	Pfizer	Арреал	
}	AO	WO 2004/078732 A1	09-16-2004	Aventis Pharma S.A.		
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	AX	WO 97/29748 A1	08-21-97	Bristol-Myers Squibb Company		

Examiner Signature	I -	ate onsidered		

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Translation is attached.

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Application Number

Filing Date

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

First Named Inventor Graeme Semple Art Unit 1614

(Use as many sheets as necessary)

Examiner Name Unknown 2 15 59.US2.PCT Sheet of Attorney Docket Number

		FOREIGN PA	TENT DOCUM	MENTS		
Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³ - Number ⁴ - Kind Code ⁵ (<i>if known</i>)	Publication Date/Filing Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	۳°
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Examiner Signature	Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet

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Application Number	10/560,332	
Filing Date	09/08/2006	1.
First Named Inventor	Graeme Semple	12
Art Unit	1614	13
Examiner Name	Unknown	
Attorney Docket Number	59.US2.PCT	

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Examiner Initials*	Cite No.1	Foreign Patent Document Country Code ³ - Number ⁴ - Kind Code ⁵ (<i>if known</i>)	Publication Date/Filing Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T [®]
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	CE	WO2006/023750	03-02-2006	Merck & Co., Inc.		
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Examiner Signature	Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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 Application Number
 10/560,332

 Filing Date
 09/08/2006

 First Named Inventor
 Graeme Semple

 Art Unit
 1614

 Examiner Name
 Unknown

(Use as many sheets as necessary)

Sheet 4 of 15 Attorney Docket Number 59.US2.PCT

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		NON PATENT LITERATURE DOCUMENTS	·
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T 2
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Signature	Considered	

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Substitute for form 1449B/PTO Complete if Known **Application Number** 10/560,332 INFORMATION DISCLOSURE Filing Date 09/08/2006 STATEMENT BY APPLICANT First Named Inventor Graeme Semple Art Unit 1614 (Use as many sheets as necessary) Examiner Name Unknown 15 59.US2.PCT Sheet Attorney Docket Number

		NON PATENT LITERATURE DOCUMENTS	-
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
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Signature	Considered	
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	DY	LUYCKX et al., "Facteurs influencant la secretion de glucagon pancreatique et extrapancreatique," Acta Isotopica, (1970), 10(3-4), 269-84	
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	EA	HAVEL et al., " Effects of 5-methylpyrazole-3- carboxylic acid (MPCA) on fat mobilization, ketogenesis and glucose metabolism during exercise in man," Advan. Exp. Med. Biol., (1969), 4 105-15	
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	ED	BIZZI et al., "The hypersensitivity of adipose tissue to norepinephrine and other lipolytic agents during blockade of free fatty acids (FFA) mobilization, " <i>Biochemical Pharmacology</i> , (1969), 18(9), 2053-60	
	EE	TAMASI et al., "Comparison of the Antilipemic Effect of Nicotinic Acid (NA) and 3-Methylpyrazole-5-Carboxylic Acid (MPC) in rats," <i>Biochemical Pharmacology</i> , (1968), 17(9), 1789-94	
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Examiner	Date	
Signature	Considered	

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Substitute for form 1449B/PTO Complete if Known Application Number 10/560,332 INFORMATION DISCLOSURE Filing Date 09/08/2006 STATEMENT BY APPLICANT First Named Inventor Graeme Semple Art Unit 1614 (Use as many sheets as necessary) Examiner Name Unknown 59.US2.PCT Sheet of Attorney Docket Number

	,	NON PATENT LITERATURE DOCUMENTS	1
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	EG	KUPIECKI et al., "Effects of 5-Methylpyrazole-3-carboxylic acid (U-19425) and nicotinic acid on lipolysis in vitro and in vivo and on cyclic-3',5'-AMP phosphodiesterase," Journal of Pharmacology and Experimental Therapeutics, (1968), 160(1), 166-70	
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	EJ	FANG, "Salicylate hypoglycemic action in alloxan-diabetic rats and structural relationships," Archives Internationales de Pharmacodynamie et de Therapie, (1968), 176(1), 193-208	
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	EN	GERRITSEN et al., "Development of Tachyphylaxis to the Antilipolytic, Hypoglycemic Agent, 5-Methylpyrazole-3-carboxylic Acid, U-19425," Proceedings of the Society for Experimental Biology and Medicine, (1967), 126(2), 524-9	
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	EQ	HO et al., "Insulin-Like Action of Quabain I. Effect on Carbohydrate Metabolism," Biochimica et Biophysica Acta, (1967), 144(1), 61-73	
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Examiner	Date		
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Substitute	for form 1449B/PT	0			Complete if Known	
INFO		Die	CLOSUBE	Application Number	10/560,332	1
			CLOSURE	Filing Date	09/08/2006	13/
STATEMENT BY APPLICANT		First Named Inventor	Graeme Semple	13		
				Art Unit	1614	,
	(Use as many sh	eets as	necessary)	Examiner Name	Unknown	
Sheet	8	of	15	Attorney Docket Number	59.US2.PCT	

	,	NON PATENT LITERATURE DOCUMENTS	·
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T 2
	EU	VETULANI, "The metabolic activity of some isoxazole and pyrazole derivatives," Dissertationes Pharmaceuticae et Pharmacologicae, (1966), 18(6), 573-84	
	EV	SMITH et al., "5-Methylpyrazole-3-carboxylic Acid. The Potent Hypoglycemic Metabolite of 3,5- Dimethylpyrazole in the Rat," Journal of Medicinal Chemistry, (1965), 8(3), 350-3	
	EW	TABAK et al., "Chromatography of Pyrazole Derivatives on Acetylated Paper," Journal of Chromatography, (1965), 17(3), 520-7	
***************************************	EX	FROESCH et al, "Insulin Inhibition of Spontaneous Adipose Tissue Lipolysis and Effects upon Fructose and Glucose Metabolism," Molecular Pharmacology, (1965), 1(3), 280-96	
	EY	SMITH et al., "Metabolism of 3,5-dimethylpyrazole-C ¹⁴ in the rat," <i>Journal of Pharmacology and Experimental Therapeutics</i> , (1965), 150(2), 316-21	
	EZ	HAMLIN et al., "Relationship between in vitro dissolution rates and solubilities of numerous compounds representative of various chemical species," <i>Journal of Pharmaceutical Sciences</i> , (1965), 54(11), 1651-3	
	FA	GERRITSEN et al., "The effect of 5-Methylpyrazole-3-Carboxylic Acid on Carbohydrate and Free Fatty Acid Metabolism," Journal of Pharmacology and Experimental Therapeutics, (1965), 150(3), 491-8	
	FB	MARSHUPTA et al., "The solubility of propylene in aromatic hydrocarbons," Khim. Prom., (1965), 41(8), 585-7	
	FC	RINGEL et al., "Darstellung and Aminolyse des 1,1,1-Trichloracetylacetons," Journal fuer Praktische Chemie, (Leipzig) (1964), 26(5-6), 333-9	
	FD	GRANDBERG, "Pyrazoles XXXIV. Ultraviolet Spectra of Pyrazole Systems," Zhurnal Obshchei Khimii, (1963), 33 519-25	
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Examiner Name

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Unknown Sheet 59.US2.PCT of Attorney Docket Number

	S	NON PATENT LITERATURE DOCUMENTS	
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	FI	DAL MONTE et al., "Ricerche sugli eterociclici: spettri di assorbimento U.V. e proprieta cromoforiche," Gazzetta Chimica Italiana. (1956), 86 797-848	
	FJ	DAL MONTE et al., "Ricerche nella serie dei pirazoli: Spettri U.V. di alcuni metal-, carbossi- e fenil-pirazoli," Bollettino Scientifico della Facolta di Chimica Industriale di Bologna, (1954), 12 147-9	
	FK	AINSWORTH et al., "Reactions of Hydrazines with y-pyrones," Journal of the American Chemical Society, (1954), 76, 3172-4	
	FL	LLOYD et al., "The Dissociation Constants of Cupric Salts of Some Monocarboxylic Acids," Journal of the Chemical Society, (1951), 1786-9	
	FM	PINO, "Le Costanti di dissociazione di alcuni derivati della serie del pirazolo e dell' isossazolo," Annali di Chimica, (Rome, Italy) (1950), 40 575-92	
	FN	HENRY et al., "Aromatic Isocyanates as Reagents for the Identification of Some Heterocyclic Compounds," Journal of the American Chemical Society, (1949), 71, 2297-2300	
	FO	HUTTEL et al., "Uber die Loslichkeit der Pyrazol-und Triazolaldehyde in Alkalien," Ann., (1947), 558, 34-47	
	FP	MUSANTE et al., "La degradazione di Curtius applicata ad alcuni acidi pirazolcarbonici," Gazzetta Chimica Italiana, (1947), 77, 182-98	
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	FR	DEWAR <i>et al.</i> , "Sulphanilamides of Some Aminopyrazoles, and a Note on the Application of <i>p</i> -Phthalimidobenzenesulphonyl Chloride to the Synthesis of Sulphanilamides," <i>Journal of the Chemical Society</i> , (1945), 114-16	
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INFORMATION DISCLOSURE

STATEMENT BY APPLICANT

Complete if Known

Application Number 10/560,332

Filing Date 09/08/2006

First Named Inventor Graeme Semple

 Frist Named Inventor
 Graeme Semple

 Art Unit
 1614

 Examiner Name
 Unknown

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Sheet 10 of 15 Attorney Docket Number 59.US2. PCT

	F	NON PATENT LITERATURE DOCUMENTS	
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	FW	YAMANAKA et al., "Sytheses of Heteroaromatic Carboxylic Acids Closely Related to Fusaric Acid," Chemical & Pharmaceutical Bulletin, (1983), 31(12), 4549-53	
	FX	KESKIN, "Semikarbazid'in α,γ-diketoasitler ve bunlarin etil esterleri uzerine etkimesi," Rev. faculte Sci. Univ. Istanbul,(1944), 9A, 81-9	
	FY	HUO et al., "Methyl 4-bromo-1,3-dimethylpyrazole-5-carboxylate," Acta Crystallographica, Section E: Structure Reports Online, (2003), E59(12), o2013-o2014	
	FZ	EHLERT et al., "Polynuclear pyrazolate complexes of copper. Crystal and molecular structures of," Canadian Journal of Chemistry, (1992), 70(8), 2161-73	
	GA	ROJAHN et al., "Beitrag zur Kenntnis der Rosenmundschen Aldehydsynthese im heterocyclischen system," Arch. Pharm., (1926), 264, 337-47	
	GB	MORGAN et al., "CLII Substitution in the Pyrazole Series. Halogen Derivatives of 3:5-Dimethylpyrazole," Journal of the Chemical Society, Transactions, (1923), 123 1308-18	
	GC	BANKS et al., "Fluorocarbon Derivatives of Nitrogen. Part 8. Reactions Between Heteroaromatic N-Imines (N-Iminopyridinium and N-Iminoquinolinium Ylide) and Perfluoropropene, 2H-Pentafluoropropene, Perfluorobut-2-ene, Perfluoro-(2-methylpent-2-ene), Perfluorobut-2-yne, and Perfluoropyridine: Synthesis of Fluorinated 3-Azaindolizines (Pyrazolo[1,5-a]-pyridines)," Journal of the Chemical Society, Perkin Transactions 1, (1982), (7), 1593-600	
	GD	FROESCH et al., Effects of 5-methylpyrazole-3-carboxylic acid on adipose tissue. I. Inhibition of lipolysis, effects on glucose, fructose, and glycogen metabolism in vitro and comparison with insulin. <i>Molecular Pharmacol.</i> (1967), 3(5), 429-41	
	GE	MUGNAINI et al., Heterocyclic syntheses with propargyl alcohol and butynediol. II. Classe sci. fis., mat. e nat. (1953), 14, 275-80	
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	GG	HÜTTEL Über einige Aldehyde der Pyrazol- und der 1.2.3-Triazol-Reihe. Berichte der deutschen chemischen Gesellschaft (A and B Series) 74(10), 1941, 1680-1687	
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Application Number	10/560,332	
Filing Date	09/08/2006	
First Named Inventor	Graeme Semple	[
Art Unit	1614	127
Examiner Name	Unknown	13
Attorney Docket Number	59. US2.PCT	

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15 Sheet 11 of

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	GI	MELANI et al., Synthesis of 5H-10,11-dihydropyrazolo[5,1-c][1,4]benzodiazepine derivatives. II. Journal of Heterocyclic Chemistry (1984), 21(3), 813-15	
	GJ	KLAGES et al., Pyrazoles from 1:3-diketones and alkyl diazoacetates. Journal fuer Praktische Chemie (1902), 65(ii), 387-93	
	GК	OWEN et al., Olefinic acids. II. Reactivity of a-bromoacrylic acid and some related compounds. Journal of the Chemical Society (1947), 1030-4	
	GL	ABDALLAH et al., Diazoacetaldehyde dimethyl acetal: a new route to cyclopropane aldehydes and formylpyrazoles. Tetrahedron Letters (1980), 21(23), 2239-42	
	GM	International Search Report, WO 2005/011677, 12/10/2004	
	GN	ALTSCHUL et al., Influence of nicotinic acid on serum cholesterol in man. Archives of biochemistry (1955), 54(2), 558-9	
	GO	TAVINTHARAN et al., The benefits of niacin in atherosclerosis. Current atherosclerosis reports (2001), 3(1), 74-82	
	GP	CARLSON et al., Nicotinic acid: the broad-spectrum lipid drug. A 50th anniversary review. Journal of Internal Medicine (2005), 258(2), 94-114	
-	GQ	LORENZEN et al., Characterization of a G protein-coupled receptor for nicotinic acid. Molecular Pharmacology (2001), 59(2), 349-357	
	GR	SOGA et al., Molecular identification of nicotinic acid receptor. Biochemical and Biophysical Research Communications (2003), 303(1), 364-369	
	GS	TUNARU et al., PUMA-G and HM74 are receptors for nicotinic acid and mediate its anti-lipolytic effect. Nature Medicine (New York, NY, United States) (2003), 9(3), 352-355	
	GT	ZHANG et al., Niacin mediates lipolysis in adipose tissue through its G-protein coupled receptor HM74A. Biochemical and Biophysical Research Communications (2005), 334(2), 729-732	
	GU	BENYO et al., GPR109A (PUMA-G/HM74A) mediates nicotinic acid-induced flushing. Journal of Clinical Investigation (2005), 115(12), 3634-3640	
	GV	O'KANE et al., A comparison of acipimox and nicotinic acid in type 2b hyperlipidaemia. British journal of clinical pharmacology (1992), 33(4), 451-3	

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Complete if Known Application Number 10/560,332 Filing Date 09/08/2006 First Named Inventor 12/ Graeme Semple Art Unit 1614 Examiner Name Unknown Attorney Docket Number 59. US2.PCT

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NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of Cite T² Examiner the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue No. Initials ' number(s), publisher, city and/or country where published. JIRKOVSKY et al., Hypolipidemic 4,5-dihydro-4-oxo-5,5-disubstituted-2-furancarboxylic acids. GW Journal of Medicinal Chemistry (1982), 25(10), 1154-6 HUNNINGHAKE et al., Controlled trial of acifran in type II hyperlipoproteinemia. GX pharmacology and therapeutics (1985), 38(3), 313-7 SEKI et al., Studies on hypolipidemic agents. II. Synthesis and pharmacological properties of GY alkylpyrazole derivatives. Chemical & Pharmaceutical Bulletin (1984), 32(4), 1568-77 VAN HERK et al., Pyrazole Derivatives as Partial Agonists for the Nicotinic Acid Receptor. Journal GΖ of Medicinal Chemistry (2003), 46(18), 3945-3951 MAHBOUBI et al., Triglyceride modulation by acifran analogs: activity towards the niacin high and HA low affinity G protein-coupled receptors HM74A and HM74. Biochemical and Biophysical Research Communications (2006), 340(2), 482-490 FROESCH et al., Effects of 5-methylpyrazole-3-carboxylic acid on adipose tissue. II. Antilipolytic HB and hypoglycemic effects in vivo. Molecular Pharmacol. (1967), 3(5), 442-52 Beilstein Records (BRN): 10958, Chemical Name (CN):4-methyl-5-propionyl-1(2)H-pyrazole-3-HC carboxylic acid Beilstein Records (BRN): 14055, Chemical Name (CN): 4-methyl-5-propionyl-1(2)H-pyrazole-3-HD carboxylic acid ethyl ester GERRITSEN et al., Effects of 5-methylpyrazole-3-carboxylic acid, U-19425, on FFA [free fatty acid] HE mobilization. Advan. Exp. Med. Biol. (1969), 4 93-103 BIZZI et al., Correlation between the effect of drugs on plasma free fatty acids and on tissue HF triglycerides. Advan. Exp. Med. Biol. (1969), 4 201-11 GUNDERSEN et al., Effects of 5-methylpyrazole-3-carboxylic and (U-19,425) and nicotinic acid HG (NA) on free fatty acids (FFA), triglycerides (TG), and cholesterol in man. Advan. Exp. Med. Biol. (1969), 4, 213-26 KIENER, Enzymic oxidation of methyl groups in heteroarenes: a versatile method for the HH preparation of heteroaromatic carborylic acids. Angew. Chem., Int. Ed. Engl., 1992, 31(6), 774-5 AKTORIES et al., Inhibition of adenylate cyclase and stimulation of a high affinity GTPase by the ΗІ antilipolytic agents, nicotinic acid, acipimox and various related compounds. Arzneimittel-Forschung (1983), 33(11), 1525-7 PRYOR et al., Purification of maize alcohol dehydrogenase and competitive inhibition by pyrazoles. HJ Biochemistry International (1982), 4(4), 431-8

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	нү	MISHRA et al., A heteroaromatic acid from marine sponge Suberites vestigium. Indian Journal of Chemistry, Section B: Organic Chemistry Including Medicinal Chemistry (1998), 37B(2), 199-200	
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 First Named Inventor
 Graeme Semple
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 Art Unit
 1614
 Examiner Name
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. =-	IM	KOJIMA et al., Renal excretion of sodium 4-iodo-5-methylpyrazole-3-carboxylate-1311. Radioisotopes (1979), 28(5), 300-5			
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	10	FLORES et al., Synthesis of hydroxypyrazoles and 1-methyl-3-isoxazolones via haloform reactions. Tetrahedron Letters (2002), 43(28), 5005-5008			
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	IR	BARIANA et al., Nicotinic acid esters as coronary vasodilators. Journal of Medicinal Chemistry (1971), 14(4), 372-3			
	IS	HOLLAND et al., Heterocyclic tetrazoles, a new class of lipolysis inhibitors. Journal of Medicinal Chemistry (1967), 10(2), 149-54			

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